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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,241	12/02/2005	Wei Chiang Lin	14506-49286	4113
24728 7590 02/22/2010 MORRIS MANNING MARTIN LLP 3343 PEACHTREE ROAD, NE 1600 ATLANTA FINANCIAL CENTER ATLANTA, GA 30326				
EXAMINER LEPITZ, JEFFREY BRIAN				
ART UNIT		PAPER NUMBER		
3769				
NOTIFICATION DATE		DELIVERY MODE		
02/22/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/528,241

Applicant(s)

LIN ET AL.

Examiner

JEFFREY B. LIPITZ

Art Unit

3769

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/30/2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/30/2009 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/GS/US)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

Applicant's drawings filed December 30, 2009 have been fully considered and overcome the objections. The drawing objections have been withdrawn.

Applicant's arguments with respect to the prior art rejections have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-31 and 33-35, 37-39 and 41-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz et al. (20020026188), hereinafter Balbierz in view of Barton et al. (20040034342), hereinafter Barton.

Regarding claim 25, Balbierz teaches a tissue diagnostic system (Paragraph [0002]) having a tubular or elongated member or introducer (12) with one or more resilient members or electrodes (18a-e) extending through the introducer (12) that are individually deployable and coupled to an ablative source (20; Paragraphs [0047] and [0088]; Figures 1, 2, 7, 20 and 23). Balbierz also teaches a light detecting member or first optical fiber (22md; Paragraph [0058]) encased in a first tubular needle or non-energy delivery resilient member (18; Paragraphs [0055] and [0090]; Figures 8 and 21) extending through the introducer (12) that can deliver light to a spectrometer or

spectrophotometer or optical measurement device, which produces spectral signals (19) at its proximal end and collect light from tissue at its distal end (Paragraphs [0057]-[0061]; Figure 4). Balbeirz teaches that the spectrometer can include fluorescent signals derived from endogenous proteins and molecules (Paragraph [0070]). Balbeirz teaches logic resources (19lr) such as a microprocessor for analyzing and storing the tissue spectral profile (Paragraphs [0062] and [0067]; Figures 4 and 31). Barton does NOT teach providing scale markings on the tubular needle to determine the position of the optical fiber. Attention is directed to Barton who teaches a needle optical fiber (28) with markings (Paragraph [0043] and [0046]; Figure 9). It would have been obvious to include markings on the tubular members of Balbierz because by doing so a surgeon could gauge the depth of the tubular member and thus the optical fiber as it is inserted into the tissue (Barton: Abstract and Paragraphs [0043] and [0046]).

Regarding claim 26, Balbierz teaches a light source (17 or 317; Paragraph [0060]) coupled to the proximal end of a second optical fiber (22me; Paragraph [0060]). The fiber extends through the tubular member (12) and has a distal end next to the ablation site (Paragraphs [0051]-[0059]; Figures 2, 4, 7-9 and 12-14).

Regarding claim 27, Balbierz teaches a light source emitting ultraviolet light capable of generating fluorescence in the tissue (Paragraph [0072]).

Regarding claims 28-31, Balbierz teaches that the light source could be a laser or a xenon bulb emitting light in a range of 300-850 nm, which includes the ranges claimed by Applicant, or a white light source (Paragraph [0060] and [0070]). The

interaction of light with the tissue is nothing more than the intended outcome of shining light on the tissue. It does not further modify any element of the invention.

Regarding claims 33 and 37, Balbierz teaches that the first and second optical fibers (22md and 22me) could extend through the first tubular needle or resilient member (18; Paragraphs [0055] and [0058]; Figures 8a-c). In a second embodiment of Balbierz, second optical fiber (22me) is encased in a second hollow needle (18e; Paragraph [0058]; Figure 8d).

Regarding claims 34 and 38, Balbierz teaches that the tubular needles (18e) are coupled with an RF ablation power source (Paragraphs [0089] and [0091]).

Regarding claims 35 and 39, Balbierz teaches an insulator or insulating cover (36) on the distal end of the needle (18; Paragraphs [0091], [0094] and [0095]; Figures 22 and 25-28). Examiner interprets all electrical insulators as thermal insulators.

Regarding claims 41-46, these claims recite substantially similar limitations to claims 27-31, rejected supra.

Balbierz as applied to claims 25, 26, 30, 31 and 37, above, and further in view of Adair (4782819).

Regarding claims 32 and 46, Balbierz does NOT teach using a halogen lamp as the light source. Attention is directed to Adair who teaches an optical catheter that can use a halogen lamp as the light source (Title, Column 9, Lines 1-5). It would have been obvious to use the lamp of Adair with the invention of Balbeirz because halogen lamps provide visible light which is used to attain spectral measurements and provide illumination.

Claims 36 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balbierz as applied to claims 25, 34 and 37 above, in combination with Hayes et al. (US 4967745), hereinafter Hayes.

Regarding claims 36 and 40, Balbierz does NOT teach transparent covers for the distal ends of the tubular needles. Attention is directed to Hayes who teaches a multi-fiber plug for a laser catheter (Abstract). Hayes teaches using a tubular member or catheter body (16), a spectrometer (64; Column 24, Lines 31-52), an optical fiber (20a-c), and a transparent optical shield or cover (12) at the distal end of the device (Column 8, Lines 5-15; Column 4, Lines 40-55; Column 7, Lines 58-61 ; Figure 1). Hayes does NOT teach electrodes. It would have been obvious to include the transparent shield of Hayes with the invention of Balbierz because including a transparent cover will allow light to be emitted and collected by the optical fibers enclosed in the needles, but also protect the fibers from damage and obstruction by tissue during ablation, or in the alternative it would have been obvious to include the electrodes of Balbierz with the invention of Hayes, because electrodes are also used for the removal of vascular obstructions (Hayes: Column 1, Lines 10-14).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY B. LIPITZ whose telephone number is (571)270-5612. The examiner can normally be reached on Monday to Thursday, 10 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on (571)272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JEFFREY B LIPITZ/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art
Unit 3769